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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,824	09/22/2003	Michael Charles Cheney	J6848(C)	1014

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EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/667,824

Applicant(s)

CHENEY ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/22/03</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Receipt of IDS dated 9-22-03 is acknowledged.

Claims 1-8 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing or overcoming in-grown hair from a shaving process, does not reasonably provide enablement for **preventing** in-grown hair from a shaving process. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Instant claims broadly recite a method of preventing in-grown hair from a shaving process, which denotes that administering the instant composition is stopping the process of hair in-growth. The instant term "prevention" denotes that the in-growth process does not occur again during the lifetime of a subject undergoing the instant treatment. A review of the instant specification does not reveal any experimental data to prove that the actual prevention is possible. In fact, instant disclosure does not provide any data with the composition described. Further, according to the instant specification, shaving process itself varies from person to person i.e., too close or close to or even insufficient in certain other area of skin being shaved. Thus, the unevenness caused by shaving process does not always result in in-grown hairs. This is further complexed with skin conditions such as elasticity, turgo, smoothness, hair type etc (instant specification page 1). Applicants admit that prior art teaches compositions for treating in-grown hair

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but state that the compositions not effective and that shaving for black males could be particularly more difficult because of the natural curvature of facial hair. Thus, there are several factors (above) contributing to the difficulty in overcoming in-grown hair compositions. In addition, instant claims do not state if the claimed method is achieved in any particular group or population and instead encompasses all kinds of skin types and textures. Further, applicants have not shown or described if the treatment is effective for any length of time i.e., years and that the treatment is successful in completely stopping from in-grown hair, in any type of skin and any type of hairs. Absent such a data and also in the absence of any description as to the dosage, duration of treatment, age of the subjects etc., one of an ordinary skill in the art would have to perform undue experimentation to practice the claimed prevention because one does not know the required duration of the claimed treatment so as to achieve the "prevention". The instant disclosure at the most enables a skilled artisan in only treating or reducing the problem of in-grown hair after shaving the skin with the claimed composition but does not enable a skilled artisan to continue the treatment for ever so as to achieve a permanently effect. For prosecution purposes, instant term "preventing" is construed as "treating or reducing or overcoming".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/800,810 (USPGPUB No 2005/0202054 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant invention as well as the co-pending application claims a method of overcoming in-grown hair by the application of a composition comprising malonic acid salt. Both sets of applications employ neutralized malonic acid and also recite the same step of applying the composition to the skin prior to or concurrent with or subsequent to removing hair by razor action. Thus, both inventions are of identical scope. Instant dependent claims differ from the co-pending claims in that the specific salt of instant claim is provided as a mousse or an aerosol. However in the absence of any criticality, applying a composition to the skin can be done in several conventional ways such as a crème, lotion (employing a mechanical pump) or a spray (as an aerosol), all of which are routinely employed in cosmetic field. Further, while instant claims recite the molar ratios of the half and fully neutralized malonic acid, the co-pending claims are silent with respect to

the percent neutralization and the burden is shifted to applicants to show that the salts of the co-pending application are neutralized to the extent claimed in the instant because both sets of claims employ the same acid salt and for the same purpose.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/767,679 (USPGPUB NO. 2004/0202869) in view of US 4,867,967 ('967) and JP 07206626 (JP) or in view of US 7,067,556 ('556) in view of JP.

The claims of the co-pending application are directed to a composition comprising terpenoids fragrance and malonic acid salt, in particular with the same neutralization ratio (full: partial neutralization) as claimed. However, co-pending claims do not recite the claimed use.

JP teaches that dicarboxylic acid salts such as sodium salt of malonic acid possess good antimicrobial and antiseptic properties and can be used in skin cosmetic compositions. JP fails to teach the claimed method.

The invention of '556 and '967 are directed to topical antimicrobial compositions. Both '556 and '967 teach that antimicrobial compositions containing effective amount of an antimicrobial agent are effective in treating pseudofolliculitis or in -grown hairs (col. 5, L 40-61 of '56, col. 6, L 18-37 of '556; abstract, col. 3, L 9-22, L 55-67 col. 4, L 41-44). Thus, it would have been obvious for one of an ordinary skill in the art at the time of the

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instant invention was made to employ the composition of co-pending claims, comprising malonic acid salts, for treating in grown hairs and pseudofolliculitis because JP teaches that malonic acid salts are effective antimicrobial agents and also possess very low skin irritancy when applied in cosmetic compositions and '967 as well as '556 suggest that a method to treat pseudofolliculitis or in-grown hairs should have superior disinfecting, antimicrobial properties so as to reduce the secondary infections that cause pseudofolliculitis. A skilled artisan would have expected to achieve a treatment for in-grown hairs and pseudofolliculitis with the malonic acid salts of co-pending application because the claimed compounds also possess antimicrobial, antiseptic and disinfectant properties and cause no skin irritation.

4. Claims 1-8 are directed to an invention not patentably distinct from claims 1-5 of commonly assigned 10/767,679 (USPGPUB NO. 2004/0202869). See above explanation.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/767,679 (USPGPUB NO. 2004/0202869), discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the

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conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over 10/767,679 (USPGPUB NO. 2004/0202869) in view of US 4,867,967 ('967) and JP 07206626 (JP) or in view of US 7,067,556 ('556) in view of JP.

The co-pending application ('679) teaches a composition comprising terpenoids fragrance and malonic acid salt, in particular with the same neutralization ratio (full: partial neutralization) as claimed (paragraphs 0016-0024). '679 further teach that the composition may be used as shaving creams, depilatories, in the form of creams, aerosol packages etc., but does not explicitly state the claimed method.

JP teaches that dicarboxylic acid salts such as sodium salt of malonic acid possess good antimicrobial and antiseptic properties and can be used in skin cosmetic compositions. JP fails to teach the claimed method.

The invention of '556 and '967 are directed to topical antimicrobial compositions. Both '556 and '967 teach that antimicrobial compositions containing effective amount of an antimicrobial agent are effective in treating pseudofolliculitis or in -grown hairs (col. 5, L 40-61 of '56, col. 6, L 18-37 of '556; abstract, col. 3, L 9-22, L 55-67 col. 4, L 41-44). Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ the composition of co-pending claims, comprising malonic acid salts, for treating in grown hairs and pseudofolliculitis because JP teaches that malonic acid salts are effective antimicrobial agents and also possess very low skin

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irritancy when applied in cosmetic compositions and '967 as well as '556 suggest that a method to treat pseudofolliculitis or in-grown hairs should have superior disinfecting, antimicrobial properties so as to reduce the secondary infections that cause pseudofolliculitis. A skilled artisan would have expected to achieve a treatment for in-grown hairs and pseudofolliculitis with the malonic acid salts of co-pending application because the claimed compounds also possess antimicrobial, antiseptic and disinfectant properties and cause no skin irritation. Further, '967 teach that the composition can be used in the form of a crème, lotion, lotion, salve etc (col. 4, L 40-44), after or before shaving (examples and claim of '967) and also using electric razors as an alternative to mechanical razors (col. 2). Therefore, the timing of application of the instant composition and the combination of the instant composition and an electric razor are within the scope of a skilled artisan.

6. Claims 1 and 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 07206626 (JP) in view of US 4,867,967 ('967) OR JP in view of US 7,067,556 ('556).

JP teaches that dicarboxylic acid salts such as sodium salt of malonic acid possess good antimicrobial and antiseptic properties and can be used in skin cosmetic compositions. While JP fails to teach ammonium salt of malonic acid, JP teaches sodium salt and in the absence of any unexpected advantage of a specific salt form over the other, a skilled artisan would have expected the same antimicrobial and

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antiseptic activity with the any salt of malonic acid. JP does not teach the claimed method.

The invention of '556 and '967 are directed to topical antimicrobial compositions. Both '556 and '967 teach that antimicrobial compositions containing effective amount of an antimicrobial agent are effective in treating pseudofolliculitis or in -grown hairs (col. 5, L 40-61 of '56, col. 6, L 18-37 of '556; abstract, col. 3, L 9-22, L 55-67 col. 4, L 41-44). Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ the malonate comprising composition of JP for treating in grown hairs and pseudofolliculitis because '967 as well as '556 suggest that a method to treat pseudofolliculitis or in-grown hairs should have superior disinfecting, antimicrobial properties so as to reduce the secondary infections that cause pseudofolliculitis and malonic acid salts are effective antimicrobial agents (JP). A skilled artisan would have expected to achieve a treatment for in-grown hairs and pseudofolliculitis with the malonic acid salts of JP because the claimed compounds also possess antimicrobial, antiseptic and disinfectant properties and cause no skin irritation. Further, '967 teach that the composition can be used in the form of a crème, lotion, lotion, salve etc (col. 4, L 40-44), after or before shaving (examples and claim of '967) and also using electric razors as an alternative to mechanical razors (col. 2). Therefore, the timing of application of the instant composition and the combination of the instant composition and an electric razor are within the scope of a skilled artisan.

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7. Claim 2 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 07206626 (JP) in view of US 4,867,967 ('967) OR JP in view of US 7,067,556 ('556) as applied to claims 1 and 3-8 above, and further in view of US 5,641,495 to Jokura ('495).

JP does not teach the claimed ratio of neutralization of malonic acid.

'495 teach a skin cosmetic composition comprising ceramides, a dicarboxylic acid and a salt of dicarboxylic acid, for moisturizing the keratinous layer of the skin. In particular, '495 teach malonic acid and its salts, including the claimed ammonium salts (col. 2, L 30-50). Thus a skilled artisan would have employed an ammonium salt of malonic acid in place of the sodium salt of malonic acid and still expect to achieve the same effect because '495 teach that the various salts of malonic acid are equivalent. With respect to the claimed neutralization, while '495 fails to teach the claimed ratio, '495 suggests adding a salt form of the acid (assuming complete neutralization) or adding acid followed by addition of an alkali to the composition to thereby form the aimed salt by neutralization within the system (col. 3, L 45-50). Thus, in the second option, a completely neutralized salt is not formed and the neutralization process occurs within the system, suggesting a complete neutralization is not an absolute requirement. In this regard, applicants have not shown any unexpected advantage with respect to the claimed full and partial neutralization. Therefore, absent such criticality, choosing a completely neutralized salt or partially neutralized salt or a mixture thereof in the composition of JP would have been within the scope of skilled artisan because

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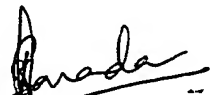
according to '495, both forms of salt are effective in providing a moisturizing effect on the skin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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January 5, 2007


LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER